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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,691	02/14/2001	Robert B. Harris	006338-017	8872

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EXAMINER	
MAYES, LAURIE A	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 08/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,691	HARRIS ET AL.	
	Examiner	Art Unit	
	Laurie Mayes	1653	

-- The MAILING DATE of this communication appears on th cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *4-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-3 and new claims 7-9, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the methods are related as they all exploit the same endotoxin-binding property of the claimed molecules. This is not found persuasive because the methods involve different steps. The method of Group I comprises the steps of administering to a patient the molecules to treat sepsis while the method of Group II comprises labeling the molecule, permitting the molecule to bind to an endotoxin and detecting a labeled bound molecule in vitro and Group III comprises removing an endotoxin from a sample in an assay, for example, by binding the molecule to a solid support, permitting the bound molecule to bind to an endotoxin and collecting the remaining sample. Further, the method of Group I is classified in class 514, subclass 2 and would require a search of over 4,300 US patents in a patent database while the method of Group II is classified in class 435, subclass 7.1 would require a search of over 4,000 different patents and Group III which is classified in class 530, subclass 412 would require a search of an additional 1,000 patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and searches required for each, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The use of the trademark has been noted in this application (ENDOSAFE LIMULUS AMEBOCYTE LYSATE ENDOCHROME-K, p. 13, line 9, for example). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Information Disclosure Statement

The listing of references in the specification on pages 18-19 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 7-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,877,153 (Harris et al.) in view of Eran et al. (H1509) and in further view of Aston (US 5,506,204). Harris et al. teach heparin antagonist peptides that have 100% sequence identity to SEQ ID NOS: 2-4 of the present invention (see attached copy of sequence alignments and see also SEQ ID NOS: 10, 1 and 11, respectively, of Harris et al.). Harris et al. do not teach a method of administering these peptides to treat sepsis.

It is known in the art that heparin binds to fibronectin and leads to reduced levels of fibronectin which have been found in patients with sepsis and that the replenishment of fibronectin, by blocking the action of heparin via a heparin antagonist, for example, treats sepsis and leads to clinical improvement of such patients. (Eran et al. US H1509, col. 2, lines 25-35). Eran et al. does not teach a peptide with sequence identity to SEQ ID NOS: 2-4 of the present invention.

Aston teaches a method of treating septic shock by administering a protein in combination with an antibiotic (see claim 2 of Aston) when the life-threatening inflammatory condition has a bacterial etiology (col. 2, lines 18-25) and a pharmaceutical carrier (col. 18, lines 25-30).

Given that the peptides taught by Harris et al. are antagonists of heparin, that a heparin antagonist that blocks the action of heparin and leads to reduced levels of fibronectin and leads to the improvement of sepsis as taught by Eran et al. and that it is often useful to add a pharmaceutical carrier and an antibiotic when treating sepsis in case the condition has a bacterial etiology as taught by Aston, it would have been obvious to one of ordinary skill in the art at the

time of the invention by the applicant to administer via a pharmaceutically acceptable carrier and in conjunction with an antibiotic Harris et al.'s heparin-antagonist peptides to treat sepsis. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Claims 1-3 and 7-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,200,955 (Harris et al.) in view of Eran et al. (H1509) and in further view of Aston (US 5,506,204). Harris et al. teach heparin antagonist peptides that have 100% sequence identity to SEQ ID NOS: 3 and 5 of the present invention (see attached copy of sequence alignments and see also SEQ ID NOS: 1 and 8, respectively, of Harris et al.). Harris et al. do not teach a method of administering these peptides to treat sepsis.

It is known in the art that heparin binds to fibronectin and leads to reduced levels of fibronectin which have been found in patients with sepsis and that the replenishment of fibronectin, by blocking the action of heparin via a heparin antagonist, for example, treats sepsis and leads to clinical improvement of such patients. (Eran et al. US H1509, col. 2, lines 25-35). Eran et al. does not teach a peptide with sequence identity to SEQ ID NOS: 2-4 of the present invention.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. (US 6,200,955) in view of Eran et al. (H1509) and in further view of Aston (US 5,506,204). Harris et al. teach heparin antagonist peptides that have 100% sequence identity to SEQ ID NOS: 3 and 5 of the present invention (see attached copy of sequence alignments and see also SEQ ID NOS: 1 and 8, respectively, of Harris et al.). Harris et al. do not teach a method of administering these peptides to treat sepsis.

It is known in the art that heparin binds to fibronectin and leads to reduced levels of fibronectin which have been found in patients with sepsis and that the replenishment of fibronectin, by blocking the action of heparin via a heparin antagonist, for example, treats sepsis and leads to clinical improvement of such patients. (Eran et al. US H1509, col. 2, lines 25-35). Eran et al. does not teach a peptide with sequence identity to SEQ ID NOS: 2-4 of the present invention.

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in conjunction with an antibiotic Harris et al.'s heparin-antagonist peptides to treat sepsis. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
August 13, 2003

Christopher S. Low

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